



Psychotropic Medication 2

Value Data Sheet 4071 CAL P PS2

Calibrators for LC-MS/MS Assay

REF 4071 CAL P PS2

LOT 09B24/S

 2026/01

IVD For in vitro diagnostic use

Diagnotix BV
De Plassen 4
9902 SE Appingedam
The Netherlands

+31 (0)596 - 20 10 62
info@diagnotix.com
order@diagnotix.com

Document version: 1.0
Replaces:
Date of release: 27-02-2024

Intended use:

The intended use of this product is calibrating the PS2 assay. These lyophilized PS2 calibrators are prepared from human serum. Stabilizers are added to stabilize the analytes for accurate calibration of the PS2 procedure.

After reconstitution these lyophilized calibrators should be treated as a patient sample.

Reconstitution:

Add exactly 500 µl of deionized water to the vial and let stand for 15 minutes.

Swirl the vial carefully and mix thoroughly. Let the vial stand for another 15 minutes and swirl one last time. Use the solution as a patient sample when all material is dissolved.

Storage and Stability

This product will be stable until the expiration date when stored unopened at 2 - 8 °C.

After reconstitution the stability of Olanzapine, Risperidone and 9-OH-risperidone is:

5 days at 4 °C

1 month at -20 °C

Aripiprazole, Quetiapine, Clozapine and Haloperidol cannot be stored after reconstitution.

The stated stabilities are only valid in case of no bacterial contamination.

Avoid repeated freezing and thawing.

Caution:

The serum used for manufacturing the calibrators has been tested and found free from infectious and contagious diseases. Nevertheless, the calibrators should be considered as potentially infectious and treated with appropriate care.

Pack size:


PS2 Calibrator Set

6 x 2 x 500 µl, Calibrator 1 - 6

Notes:

The concentrations of the analytes are chosen in ranges where valid results can be obtained. The variation of the filling volume (CV) is < 1 %.

Concentrations:

4071 CAL P PS2 	09B24/01 2026/01	09B24/02 2026/01	09B24/03 2026/01	09B24/04 2026/01	09B24/05 2026/01	09B24/06 2026/01
Analyte	Cal 1 4073 P PS2	Cal 2 4074 P PS2	Cal 3 4075 P PS2	Cal 4 4076 P PS2	Cal 5 4077 P PS2	Cal 6 4078 P PS2
Aripiprazole	0 µg/l	13.4 µg/l	26.9 µg/l	122 µg/l	329 µg/l	675 µg/l
Clozapine	0 µg/l	63.6 µg/l	138 µg/l	277 µg/l	653 µg/l	1157 µg/l
Haloperidol	0 µg/l	1.77 µg/l	4.42 µg/l	11.0 µg/l	21.3 µg/l	45.7 µg/l
Olanzapine	0 µg/l	5.48 µg/l	12.4 µg/l	48.2 µg/l	120 µg/l	245 µg/l
Quetiapine	0 µg/l	17.5 µg/l	32.4 µg/l	135 µg/l	353 µg/l	740 µg/l
Risperidone	0 µg/l	4.69 µg/l	9.53 µg/l	17.7 µg/l	39.0 µg/l	75.1 µg/l
9-OH-Risperidone	0 µg/l	4.17 µg/l	8.13 µg/l	23.1 µg/l	60.5 µg/l	134 µg/l